

DEFENSE HEALTH BOARD FIVE SKYLINE PLACE, SUITE 810 5111 LEESBURG PIKE FALLS CHURCH, VA 22041-3206

October 4, 2007

DHB

MEMORANDUM FOR: The Honorable S. Ward Casscells, Assistant Secretary of Defense for Health Affairs

SUBJECT: Recommendations on Southern Hemisphere Influenza Vaccine for U.S. Forces – DHB 2007-03

1. References:

- Memorandum, The Joint Staff, 13 February 2006, Southern Hemisphere Influenza Vaccine for U.S. Forces.
- b) Presentation on Influenza Vaccination for the Southern Hemisphere to the Armed Forces Epidemiological Board (AFEB), 2006, by Dr. Raymond Strikas, National Vaccine Program Office, Department of Health and Human Services.
- c) Presentation on Southern Hemisphere Influenza Vaccines and Circulating Strains to the AFEB, 2006, by Dr. Ann Moen, Centers for Disease Control and Prevention, Department of Health and Human Services.
- d) Presentation on Influenza Vaccine for Southern Hemisphere to the AFEB, 2006, by Dr. John Grabenstein, Military Vaccine (MILVAX) Agency.
- e) Presentation on Influenza Outbreak During Talisman Saber 2005 to the AFEB, 2006, by CDR Fred Landro, Medical Corps, U.S. Navy.
- f) Presentation on Global Circulation of Influenza Viruses and Evaluation of the Southern Hemisphere Vaccine Recommendations at the Vaccine Research Conference, 2006, by Dr. Mark Miller, Fogarty International Center, National Institutes of Health.
- g) Nelson MI, Simonsen L, Viboud C, Miller MA, Holmes EC. Phylogenetic Analysis Reveals the Global Migration of Seasonal Influenza A Viruses. PLoS Pathog 2007;3(9):e131.
- 2. At the request of The Joint Staff, the Defense Health Board has addressed concerns regarding the lack of Southern Hemisphere Influenza vaccines for United States service members stationed or deployed in the Southern Hemisphere. Specifically, the Joint Staff Surgeon asked the Board to research and make recommendations regarding the following questions.
 - a) Are the common circulating influenza viruses different enough to annually warrant separate Northern and Southern hemispheric vaccines?

SUBJECT: Recommendations on Southern Hemisphere Influenza Vaccine for U.S. Forces – DHB 2007-03

- b) Is there insufficient cross-reactivity between the two vaccines to annually warrant DOD procurement of the two separate hemispheric influenza vaccines?
- c) Is it practical for DOD to annually procure a FDA-licensed Southern Hemisphere influenza vaccine?
- d) What are the consequences of not procuring a FDA-licensed Southern Hemisphere influenza vaccine?
- 3. The Board received a number of briefings and presentations regarding Southern Hemisphere influenza epidemiology, influenza vaccines, the vaccine licensure process, and alternative approaches for the acquisition and use of vaccines for service members. The question was subsequently referred to the Board's Subcommittee on Infectious Disease Control for further review.
- 4. The Infectious Disease Control Subcommittee conducted an extensive literature review and met telephonically in preparatory session on several occasions. The Subcommittee reviewed data regarding the concordance and discordance between the Northern Hemisphere and the Southern Hemisphere recommendations over 16 influenza seasons, as well as the degree of hemispheric matching within one season. The Subcommittee also reviewed the timing of the vaccine recommendations relative to the circulation of the new stains. The data show that Southern Hemisphere presentation of a particular influenza strain precedes Northern Hemisphere presentation at a frequency approximately equal to Northern Hemisphere precedence. In reviewing 18 different strain changes, an equal number occurred in each hemisphere, indicating no difference in virus shift or drift between hemispheres.
- 5. Seasonal influenza infection typically peaks at different times depending on hemisphere (July in the Southern Hemisphere, January in the Northern Hemisphere) and manufacturers time the release of their vaccine to precede these peaks. However, influenza is endemic year round in tropical and some subtropical areas. The available vaccines, whether designed for Northern or Southern Hemispheres, may have little correlation to the endemic topical influenza strains. Even when tropical influenza strains are included in Southern Hemisphere vaccines, substantial numbers of service members deployed to regions such as Southeast Asia could experience "off season" influenza risk with limited vaccine protection given the timing of Southern Hemisphere vaccine administration and limitations based on prescribed vaccine expiration dates.
- The Defense Health Board deliberated the Infectious Disease Control Subcommittee's
 findings in open session at the Board's September 19, 2007 open meeting. Based of these
 deliberations, the Board provides the following recommendations.
 - a) The Board does not recommend the use of a Southern Hemisphere influenza vaccine for U.S. Forces at the present time. If an FDA licensed vaccine for the Southern Hemisphere becomes available, the Board will reconsider the issue.

SUBJECT: Recommendations on Southern Hemisphere Influenza Vaccine for U.S. Forces – DHB 2007-03

- b) The Board believes that apart from uncommon outbreaks, the overall mission impact of Southern Hemisphere influenza is minimal. Nonetheless, given the Department's increasing commitment to the Southern Hemisphere, including proposed plans for a combatant command in Africa (AFRICOM), the Board encourages discussions between the Department and vaccine manufacturers regarding U.S. licensure of Southern Hemisphere influenza vaccine. In the event that a new sub-strain causes widespread illness, the DOD may consider Investigational New Drug (IND) or Emergency Use Authorization (EUA) approaches to acquisition and use of Southern Hemisphere influenza vaccines.
- c) The Board also encourages continuing discussion and collaboration between the Department of Defense and other federal agencies regarding Southern Hemisphere influenza. A substantial number of American citizens including Peace Corps workers, and employees of the Departments of State and Health and Human Services reside in the Southern Hemisphere for extended periods. A widespread influenza outbreak can potentially impact national missions and objectives.
- d) An enhanced surveillance strategy is recommended by the Subcommittee, including collaboration with other Federal agencies and influenza surveillance among military personnel in the Southern Hemisphere. In particular, the Subcommittee believes that surveillance only exists in the more developed areas of the Southern Hemisphere.
- 7. The above recommendations were unanimously approved.

FOR THE DEFENSE HEALTH BOARD:

Gregory A. Poland, M.D.

DHB President

cc:

Board Members and Consultants
DASD(C&PP)
DASD(FHP&R)
Surgeon General of the Army
Surgeon General of the Navy
Surgeon General of the Air Force
Joint Staff Surgeon
Commander, USAMRMC
USAMRIID
Joint Vaccine Acquisition Program
Library of Congress